the sensor components including nucleic components. For example, a quantitative oligonucleotide assay is described where the target binds to a receptor on the sensor and is also bound by a labeled probe. The label is capable of generating a signal that is detected by the sensor, e.g., an electrochemical sensor. For example, U.S. Pat. No. 5,837,454 is directed to a method of making a plurality of sensors with a perm-selective membrane coated with a ligand receptor that can be a nucleic component. Finally, jointly-owned U.S. Pat. No. 5,447,440 is directed to a coagulation affinity-based assay applicable to nucleotides, oligonucleotides or polynucleotides. Each of the aforementioned jointly-owned patents are incorporated by reference herein in their entireties.

[0018] It is noteworthy that jointly-owned U.S. Pat. No. 5,609,824 teaches a thermostated chip for use within a disposable cartridge applicable to thermostating a sample, e.g., blood, to 37° C. Jointly-owned U.S. Pat. No. 6,750,053 and U.S. Application Publication No. 2003/0170881 address functional fluidic elements of a disposable cartridge relevant to various tests including DNA analyses. These additional jointly-owned patents and applications are incorporated by reference herein in their entireties.

[0019] Several other patents address electrochemical detection of nucleic acids. For example, U.S. Pat. No. 4,840,893 teaches detection with an enzyme label that uses a mediator, e.g., ferrocene. U.S. Pat. No. 6,391,558 teaches single stranded DNA on the electrode that binds to a target, where a reporter group is detected by the electrode towards the end of a voltage pulse and uses gold particles on the electrode and biotin immobilization. For example, U.S. Pat. No. 6,346,387 is directed to another mediator approach, but with a membrane layer over the electrode through which a transition metal mediator can pass. U.S. Pat. No. 5,945,286 is based on electrochemistry with intercalating molecules. For example, U.S. Pat. No. 6,197,508 teaches annealing single strands of nucleic acid to form double strands using a negative voltage followed by a positive voltage. Similar patents include, for example, U.S. Pat. Nos. 5,814,450, 5,824,477, 5,607,832, and 5,527,670 that teach electrochemical denaturation of double stranded DNA. U.S. Pat. Nos. 5,952,172 and 6,277,576 teach DNA directly labeled with a redox group.

[0020] Several patents address devising cartridge-based features or devices for performing nucleic acid analyses. Such patents include, for example, a denaturing device described in U.S. Pat. No. 6,485,915, an integrated fluid manipulation cartridge described in U.S. Pat. No. 6,440,725, a microfluidic system described in U.S. Pat. No. 5,976,336 and a microchip for separation and amplification described U.S. Pat. No. 6,589,742.

[0021] Based on the forgoing description, there remains a need for a convenient and portable analysis system capable of performing nucleic acid amplification and testing.

SUMMARY OF THE INVENTION

[0022] An object of the present invention is to provide an integrated nucleic acid test cartridge capable of amplification.

[0023] A further object of the present invention is to provide an integrated nucleic acid test cartridge capable of performing extraction and amplification in a single chamber.

[0024] Another object of the present invention is to provide an integrated nucleic acid test cartridge capable of performing amplification and transferring an amplicon for detection.

[0025] A further object of the present invention is to provide an integrated cartridge for nucleic acid amplification that operates in conjunction with a controlling instrument.

[0026] An object of the present invention is to provide an integrated nucleic acid testing system and method suitable for analyses performed at the bedside, in the physician's office and other locations remote from a laboratory environment where testing is traditionally performed. The present invention particularly addresses expanding opportunities for point-of-care diagnostic testing, i.e., testing that is rapid, inexpensive and convenient using small volumes of accessible bodily fluids such as, for example, blood and buccal cells.

[0027] Another object of the present invention to provide a means of performing a DNA amplification reaction using a portable power supply, including using batteries or solar power.

[0028] Exemplary embodiments of the present invention provide a single-use nucleic acid amplification device for producing an amplicon comprising: a housing, an amplification chamber comprising an ingress with a reversible seal, an egress with a reversible seal, a sealable sample entry orifice and a first wall forming a portion of the chamber, where the first wall comprises a thermally conductive material having a first (e.g., interior) surface and a second (e.g., exterior) surface, where the exterior surface has a heating circuit and a temperature sensor, where the sample entry orifice permits a sample of nucleic acid to enter the chamber, where the ingress is connected to a conduit with a pneumatic pump means and a fluid pouch, where the egress is connected to a conduit permitting egress of the amplicon from the chamber. In one exemplary embodiment of the present invention, the pump means can comprise a flexible diaphragm capable of engaging and being actuated by a plunger on an instrument with which the device is capable of mating. In another exemplary embodiment, the pump means can comprise a flexible diaphragm capable of manual actuation. The above-mentioned fluid pouch can contain a fluid, including, but not limited to, a fluid for performing a nucleic acid amplification. Optionally, the fluid pouch can further contain one or more reagents selected from the group consisting of deionized water, a buffer material, dNTPs, one or more primers and a polymerase.

[0029] According to one exemplary embodiment of the amplification chamber of the present invention, the first wall can comprise silicon. Optionally, a second wall can comprise a plastic material. Preferably, the second wall comprising a plastic material has a wall thickness in the range of about 0.2 mm to about 5 mm, with one or more additional and optional rib supports. In a preferred exemplary embodiment of the chamber of the present invention, the first wall comprising silicon takes up about 30 to about 50 percent of the interior surface area of the chamber. More preferably, the internal volume of the chamber can be in the range of about 5 uL to about 50 uL. The ratio of the chamber surface to the chamber volume can vary widely. In a particular exemplary embodiment of the present invention, the chamber surface can range from about 50 to about 200 mm^2 compared with a chamber volume that ranges from about 5 to about 30 mm^3. The amplification chamber can have a variety of